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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,526	06/24/2003	William R. Noyes	3222.01US02	1769

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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10/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/602,526

Applicant(s)

NOYES, WILLIAM R.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-25, 27, 29-41, 43-57 and 59-64 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 13-16, 39-41, 43-57 and 59-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-25, 27, 29-38 and 62-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. §1.114, the Amendment, Applicant's Arguments/Remarks and the request for extension of time (2 months-granted), all filed 07/13/07 is acknowledged. Examiner also acknowledges Applicant's request to rejoin withdrawn claims upon allowance of the generic claims.

Applicant's arguments filed 07/13/07 have been fully considered and were found to be persuasive. Accordingly, the Final Office Action filed 02/27/07 has been withdrawn. The following are the new grounds of rejection:

Claims 1-10, 13-25, 27, 29-41, 43-57 and 59-64 are pending in this action. Claims 1, 17, 39 and 43 have been amended. New claims 63-64 have been added. Claims 1-10, 13-16, 39-41, 43-57 and 59-61 were previously cancelled. Claims 17-25, 27, 29-38 and 62-64 are rejected.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/13/07 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-25, 27, 29-38 and 62-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a first tissue location being a “rectum”, does not reasonably provide enablement for the first tissue location being tissue of “an ovary, a nerve, a cartilage, a bone and a brain” (see instant claim 20). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicant has only established ample support in the specification for the first tissue location being that of the “rectum” (specification, pp. 4-6). Applicant has not provided sufficient support for the first tissue being tissue selected from the group consisting of an ovary, nerve, cartilage, bone and a brain. A review of the instant specification on pp. 6-7 does not indicate that the disclosure of the generic term “tissue” which Applicant recites “encompasses a group of cells or an anatomical portion of a body, e.g., ovary, nerve, cartilage, bone and brain” would be sufficient to enable one skilled in the art to make and/or use the invention. The species of instant claim 20 is unpatentable.

Claims 17-25, 27, 29-38 and 62-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a biocompatible filler material made of "collagen", does not reasonably provide enablement for the selective filler materials of instant claim 21 (i.e., polyethylene glycol). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicant has only established ample support in the specification for the use of "collagen" as a suitable filler material (specification, pp. 5-6). Applicant has not presented sufficient support for any other embodiment regarding the filler materials of instant claim 21. The specification merely states at page 6, lines 7-9, that, "Other materials may be used that include natural or synthetic materials, e.g., proteins...polyethylene glycol-based materials". This disclosure is not sufficient to support the species of filler materials of instant claim 21 and is found unpatentable.

Response to Arguments

Applicant's arguments see response on pages 12-17 filed 07/13/07, with respect to the 35 U.S.C. §103(a) rejections over Tihon *et al.* (U.S. Pat. No. 5,499,994) and Gokcen (U.S. Pat. No. 6,913,744) has been fully considered and is persuasive. The rejection of claims 17-25, 27, 29-38 and 62 has been withdrawn.

Allowable Subject Matter

The following claim 17 drafted by the examiner and considered to distinguish patentably over the art of record in this application, is presented to applicant for consideration:

(Proposed claim 17):

A method of delivering a therapeutic dose of radiation to a patient comprising: (i) the initial step of injecting anesthesia and (ii) injecting saline to expand the space between the first and second tissue location, wherein the first tissue location is associated with the rectum and the second tissue location is associated with the prostate gland and introducing a biocompatible, biodegradable filler device between the first tissue location and the second tissue location to increase a distance between the first tissue location and the second tissue location, said biocompatible, biodegradable filler being collagen and introducing collagen into Denovillier's space and treating the second tissue location with a therapeutic dose of radiation, said therapeutic dose of radiation being 70 to 100 Gy, so that the presence of the filler device causes the first tissue location to receive less than 50% of the dose of radioactivity compared to the amount of the dose of radioactivity the first tissue location would have received in the absence of the filler device, wherein the filler device is removed by biodegradation of the filler device in the patient.

- Cancel claims 18-21. (The limitations of claims 18 & 19 are included in proposed claim 17. Claims 20-21 should be cancelled, as they are non-enabling).

Note: The above-recited proposed claim 17 would be allowable and any method claim(s) dependent upon claim 17 would also be allowable.

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Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 28, 2007

hns


HUMERA N. SHEIKH
PRIMARY EXAMINER